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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/092,095

03/06/2002

Brian Bates

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7590

08/09/2006

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EXAMINER

WEBB, SARAH K

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,095

Applicant(s)

BATES, BRIAN

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-50, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-50, 73 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 40-48, 50, 73, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,080,191 to Summers in view of US Patent No. 5,951,599 to McCrory, and further in view of US Patent No. US Patent No. 5,700,285 to Myers et al.

Summers discloses several stent patterns in Figures 1-5 and 21 that meet many limitations of the claims. The embodiment of the stent in Figures 1-5 is formed from a single wire (column 3, line 65), has ring segments joined by curved regions, and adjacent rings are interleaved. The embodiment in Figure 21 has a longitudinal support and is formed from a flat sheet of material. Summers states that a graft material may be attached to any of the disclosed stent frames to seal an aneurysm (column 11, lines 25-52), but Summers fails to state that the graft material only covers a portion of the stent circumference.

McCrory discloses another stent frame with a graft attached to it. As shown in Figure 2A, the graft (22) extends only a portion of the length and circumference of the frame. The graft extends *at least* 1/4 of the circumference. The graft material is an impermeable polymer that is attached to the frame by various attachment means (column 4, lines 14-19) and is intended for sealing an aneurysm. McCrory teaches that this particular configuration of the graft material allows the blood to flow through the apertures of the stent except at the neck of the aneurysm, where thrombosis is desired (column 3, lines 1-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a partial circumference graft on

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the Summers stent frame, as McCrory teaches that this configuration allows blood to flow through the stent frame apertures except at the site of the aneurysm sac. This configuration effectively seals the aneurysm without significantly affecting the flow of blood to other areas of the vessel.

Summers and McCrory fail to go into detail about the connection between the graft and stent frame, but McCrory does state that any suitable mechanism for attaching a graft material to a stent frame may be used (column 4, lines 15-18). The limitation *"secured to said support frame by folding one end of said graft material around one of said frame threads... and connecting two layers..."* is a product by process limitation. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. The prior art only needs to meet the structural requirements – the graft only needs to encapsulate the frame threads at the end of the stent and have an area of double thickness. Myers discloses another stent-graft and teaches that it is known in the art for a graft to be affixed to a stent by encapsulating the stent frame with graft layers that are attached to one another by adhesive or sutures through the stent openings (see Figure 8 and column 7, lines 54-63). Since McCrory teaches that any known attachment mechanism can be used, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the graft of the modified Summers device by either of the attachment means taught by Myers.

2. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Summers in view of McCrory and Myers, as applied above, and further in view of US Patent App. Pub. No. 2003/0139802 (Wulfman et al.).

The modified Summers device fails to configure the partial circumference graft to extend the full length of the stent. Wulfman discloses another stent frame that includes a graft (28) is disposed over *approximately* ½ of the circumference of the frame (26). Similar to McCrory, the graft material (28) is also an impermeable polymer material that is attached to the frame by various attachment means (0033). Wulfman teaches that a partial circumference graft can extend the full length of the stent as an alternative to a partial length of the stent [0029]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the graft of the modified Summers device to extend the full length of the stent, as Wulfman teaches that this simple modification allows the device to be adapted for various types of vessel irregularities.

Response to Arguments

3. Applicant's arguments filed 5/22/06 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). All of the claimed elements are shown in the prior art and there is proper motivation for combining the elements.

4. Applicant argues that McCrory teaches away from a partial circumference graft in the embodiment of Figure 3A. This embodiment is relied upon for the rejection,

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because it involves in vivo formation of a graft portion. The embodiment relied upon for the rejection is the embodiment of Figure 2A.

5. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, McCrory teaches that the partial circumference graft material allows the blood to flow through the apertures of the stent except at the neck of the aneurysm, where thrombosis is desired (column 3, lines 1-22). Summers also states that a graft material may be attached to any of the disclosed stent frames to seal an aneurysm (column 11, lines 25-52). Since both devices are directed toward stent-grafts used to seal aneurysms, the combination is proper.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

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any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW
8/1/06



JULIAN W. WOO
PRIMARY EXAMINER